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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement filed 6/25/09 after the final Office action mailed 6/8/09 fails to comply with 37 CFR 1.97(d) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

ADVISORY ACTION

2. The amendment filed 8/10/09 has been entered into the record. Claims 14, 15, 23 and 27-35 are now pending in the instant application.

Objections/Rejections Withdrawn

3. The objection to claims 17 and 27 is withdrawn in view of the amendment to claim 27 and the cancellation of claim 17.

4. The rejection of claims 17-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

5. The rejection of claims 17, 18, 21, 22, 24, 26 rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. US 2002/0025325 A1 Feb. 28, 2002 (cited previously) in view of Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000 is withdrawn in view of the cancellation of the claims.

6. The rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Chu et al. US 2002/0025325 A1 Feb. 28, 2002 (cited previously) and Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000, as applied to claims 17, 18, 21, 22, 24, 26, 27, 28, 31, 32, 33

and 35 above, further in view of Demello et al. US 5,846,830 Dec. 8, 1998 is withdrawn in view of the cancellation of the claim.

7. The rejection of claims 17, 18, 21-22, 26 and 28 rejected over Dowling et al. US 6,177,082 B1 Jan 23, 2001 in view of Gallili et al. US 6,541,001 B1 April. 1, 2003 is withdrawn in view of the amendments to the claims.

8. The rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Dowling et al. US 6,177,082 B1 Jan 23, 2001 and Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000, as applied to claims 17, 18, 21, 22, 26, 27, 28, 31, 32 and 35 above, further in view of Demello et al. US 5,846,830 Dec. 8, 1998 is withdrawn in view of the cancellation of the claim.

9. The rejection of claims 17, 22, 25, 26, rejected under 35 U.S.C. 103(a) as being unpatentable over Squires et al US 6,350,784 B1 Feb. 26, 2002 (filed March 26, 1997) in view of Reynolds et al US 5,753,244 May 19, 1998 is withdrawn in view of the cancellation of the claims.

10. The rejection of claims 18-20 and 24 under 35 U.S.C. 103(a) as being unpatentable over Squires et al US 6,350,784 B1 Fe. 26, 2002 and Reynolds et al US 5,753,244 May 19, 1998 as applied to claims 17, 22, 25, 26, 27, 32, 34 and 35 above, further in view of Callaghan et al US 6,410,062 B1 (June 25, 2002 filed Jun. 2, 2000) is withdrawn in view of the cancellation of the claims.

Rejections Maintained.

11. The rejection of claims 27, 28, 31, 32, 33 and 35 under 35 U.S.C. 103(a) as being unpatentable over Chu et al. US 2002/0025325 A1 Feb. 28, 2002 (cited previously) in view of Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000 is maintained.

Applicant's arguments and the response:

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Chu's effective dose of the vaccine is exclusively taught to be contained in the average amount of water consumed by the animals and not applied to the muzzle and then distributed to the animal's oral and nasal mucosa.

Applicant's argument is carefully considered but is not persuasive. First of all the specification defines muzzle as the facial portion of the respiratory system and rostral portion of the upper and lower jaws collectively, to include the nasal plane, nostrils, medial, lateral, dorsal and ventral borders of the nostrils, the philtrum, superior and inferior lips (labia oris) and the angle of the mouth (angulus oris). For example, Chu et al teaches administering the vaccine in drinking water to pigs or horses in a bucket or trough. When the pig lowers its snout or muzzle (which includes the nose and the mouth which are located very close together in the anatomy of said animals) into the bucket or trough, this is a direct application to the muzzle. The claims do not require that the animal absorbs the effective dose through the

nasal or oral mucosa, the claims require that the animal distributes into its oral and/or nasal cavity when said animal cleans said muzzle with its tongue.

Thus, by the animal drinking the water/vaccine mix from a bucket or trough the water/vaccine mix is applied directly to the muzzle of the pigs, goats, sheep, cattle, horses when the animal sticks its head into the bucket or trough and when said animals inherently licks it muzzle with its tongue , they will distribute the water/vaccine mix into their oral and nasal cavity.

As to the issue of the animals receiving an effective dose and that Chu et al promotes mass administration via drinking water and thus teaches away from directly applying the prophylactic composition to an animal's muzzle, Applicant's argument is carefully considered but is not persuasive. The claims as written do not state what the effective dose accomplishes. The specification does not define "effective dose". Although< claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation >in light of the specification<.). Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment."

Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). Thus, even if all the effective dose is not distributed into the nasal and/oral cavity by cleaning the muzzle with the tongue, any vaccine ingested will at least be effective to induce some immune response and achieve some positive effect. It is also noted that application of an effective dose of a prophylactic composition to the muzzle of an animal does not assure that 100% of the effective dose is cleaned off the muzzle of said animals tongue as an individual cannot control 100% the actions of the livestock animal.

Applicants argue that Gallili et al does not disclose a post-application identifier but that Gallili et al teaches the colorant for coloring the different types of vaccines which is useful against mistakes that have been made by farmers. Applicant's arguments are carefully considered but are not persuasive. Gallili et al mixes the vaccine formulation with the colorant/dye before administering the livestock. See column 11 lines 18 to 21. It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made that the dye in the vaccine/drinking water will stain the tongue of the livestock, thus letting the farmer know that the livestock has come in contact with the vaccine. Thus, the colorant/dye is both a pre and post application identifier. Also note that the instant claims do not specify how much post-application identifier is in the prophylactic composition, thus Applicants arguments concerning concentration of dye effective to be post application identifier is not commensurate with the scope of the instant claims.

Applicant agrees that some of whole body spray may hit the muzzle during the whole body spray but maintain that the effective dose is applied over the entire body not the muzzle in particular. This is carefully considered but not persuasive. As set forth above, the claims do not

specifically recite what the 'effective dose" is effective for, therefore even if all the effective dose is not distributed into the nasal and/oral cavity by cleaning the muzzle with the tongue, any vaccine ingested will at least be effective to induce some immune response and achieve some positive effect. In addition as noted, above, there is no 100% assurance that a livestock will clean with tongue 100% of the effective dose applied to the muzzle as claimed in claim 1 as the instant method relies on the behavior of the animal which is not in control of the individual applying the prophylactic composition.

The rejection is maintained over the combination of Chu and Gallili.

12. The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Chu et al. US 2002/0025325 A1 Feb. 28, 2002 (cited previously) and Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000, as applied to claims 27, 28, 31, 32, 33 and 35 above, further in view of Emery et al. US 5,906,826 May 25, 1999 is maintained.

Applicant's arguments are essentially for the same reasons set forth above and also stating that Emery et al does not teach directly applying an effective dose of such composition to the muzzle of a livestock animal wherein the animal distributes the effective dose to the animal's oral and nasal mucosa with its tongue. Applicant's arguments are carefully considered and has been addressed above.

13. The rejection of claim 34 under 35 U.S.C. 103(a) as being unpatentable over Chu et al. US 2002/0025325 A1 Feb. 28, 2002 (cited previously) and Gallili et al. US 6,541,001 B1

April. 1, 2003 filed Aug. 21, 2000, as applied to claims 27, 28, 31, 32, 33 and 35 above, further in view of Demello et al. US 5,846,830 Dec. 8, 1998 is maintained.

Applicant's arguments and the response

Applicant's arguments are essentially for the same reasons set forth above for Chu in view of Gallili and have been addressed above. Furthermore, Applicants argue that the combination of Chu, Gallili and Demello would actually result in a vaccine and fluorescein dye dissolved in water in a trough wherein the animal consumes the vaccine and dye present in the water and both are processed within the digestive system wherein the presence of the dye can be detected in the feces and urine of the livestock animal. Furthermore, Applicants argue Demello separately and not the combination of references. This is not persuasive. Demello is cited for the teaches that fluorescent dyes such as fluorescein can be applied to watering material or sprays and can be detected in feces or urine. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to substitute the dye of the vaccine of Chu and Gallili et al as combined with the UV dye of Demello et al as a way to identify which livestock animals have orally ingested the vaccines via drinking water as UV dyes can be identified in feces or urine of the said animal (Demello et al column 2 lines 13 to 19), thus resulting in the instant invention with a reasonable expectation of success.

The instant claims recite that the post-application identifiers is in the prophylactic composition. Thus, when the livestock cleans its muzzle the vaccine and post application identifier composition is distributed into the oral cavity as recited in the claim and the fluorescein is detected in feces or urine, thus the fluorescein is post application identifier that is identified in feces or urine after the livestock has distributed the vaccine and post application

identifier composition into the oral cavity. Claim 1 and 35 broadly recites post-application identifier and UV dye respectively. The claim do not recite how the post-application identifier is identified or where thus, Applicants arguments that the UV dye is physically present and readily identifiable on the exterior of the animal or inherent delays in digesting dye and purging of animal's waste or practicality of identifying a particular animal in a group of livestock is not commensurate with the scope of the claims. Furthermore, there is no definition in the specification of a "post application identification" thus the term is given its broadest reasonable interpretation. Thus, the combination of Chu, Gallili and Demello would result in the post application identification of animals who have distributed the instant composition into their oral cavity via identification of the UV dye in feces or urine thus recognizing animals who have distributed the instant composition into their oral cavity.

14. The rejection of claims 27, 31, 32 and 35 over Dowling et al. US 6,177,082 B1 Jan 23, 2001 in view of Gallili et al. US 6,541,001 B1 April. 1, 2003 is maintained.

Applicant's arguments and the response

Applicant argues that while the nebulizer device may be in proximate contact with the muzzle of an animal, the effective dose of Dowling's composition is exclusively inhaled into the animals respiratory system and does not teach direct application of an effective dose of a prophylactic composition to the muzzle and certainly does not indicate reliance on the animal's tongue to distribute the effective dose into the nasal and oral mucosa.

Applicant's argument is carefully considered but not persuasive.

As to the instant claim limitations:

Dowling teaches "applying an effective dose of a prophylactic composition directly to a muzzle of said animal" via a nebulizer places over the animal's nose and mouth.

While some of the effective dose goes directly into the nose or mouth of the animal, some of the effective dose will be deposited on the nose and mouth of the animal and via the animal's inherent behavior the animal will clean its nose and mouth and distribute some effective dose into its oral and/or nasal cavity. As set forth above, the claims do not specifically recite what the 'effective dose" is effective for, therefore even if all the effective dose is not distributed into the nasal and/oral cavity by cleaning the muzzle with the tongue, any vaccine ingested will at least be effective to induce some immune response and achieve some positive effect. In addition as noted, above, there is no 100% assurance that a livestock will clean with tongue 100% of the effective dose applied to the muzzle as claimed in claim 1 as the instant method relies on the behavior of the animal which is not in control of the individual applying the prophylactic composition. Dowling does not teach away because it teaches intranasal administration via nebulization because claim 27 does not set forth how the effective dose is applied and a nebulizer applies the composition directly to the muzzle. There is nothing in the claim that recites that the composition is applied directly to the "exterior of the muzzle"; the claim recites "directly to the muzzle". Furthermore, the Office understands the intended use or effects or benefits or purpose of the invention as described in the specification, however, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004).

Applicants arguments directed to Gallili et al are essentially for the same reasons above and have been addressed above. Gallili et al mixes the vaccine formulation with the colorant/dye before administering the livestock. See column 11 lines 18 to 21. It would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made that the dye in the vaccine/drinking water will stain the tongue of the livestock, thus letting the farmer know that the livestock has come in contact with the vaccine. Thus, the colorant/dye is both a pre and post application identifier.

15. The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Dowling et al. US 6,177,082 B1 Jan 23, 2001 and Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000, as applied to claims 27, 28, 31, 32 and 35 above, further in view of Emery et al. US 5,906,826 May 25, 1999 is maintained.

Applicant's arguments are essentially for the same reasons set forth above and also stating that Emery et al does not teach directly applying an effective dose of such composition to the muzzle of a livestock animal wherein the animal distributes the effective dose to the animal's oral and nasal mucosa with its tongue. Applicant's arguments are carefully considered and has been addressed above.

16. The rejection of claim 34 under 35 U.S.C. 103(a) as being unpatentable over Dowling et al. US 6,177,082 B1 Jan 23, 2001 and Gallili et al. US 6,541,001 B1 April. 1, 2003 filed Aug. 21, 2000, as applied to claims 17, 18, 21, 22, 26, 27, 28, 31, 32 and 35 above, further in view of Demello et al. US 5,846,830 Dec. 8, 1998 is maintained.

Applicants arguments are essentially for the same reasons as set forth above for Dowling in view of Gallili and Applicants arguments over the Demello reference set forth above. These arguments have been addressed above.

17. The rejection of claims 27, 32, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over Squires et al US 6,350,784 B1 Feb. 26, 2002 (filed March 26, 1997) in view of Reynolds et al US 5,753,244 May 19, 1998 is maintained.

Applicants argue that Squires teaches topically applying an effective dose of a medical compound to a virus caused wart on a horses muzzle (example 14 column 28) and that the medical compound is not a veterinary prophylactic composition.

Applicant's argument is carefully considered but is not persuasive. Squires et al teaches a method of treating livestock e.g. a horse to achieve positive effect on the health of the horse comprising applying topically a veterinary prophylactic compound (also a veterinary prophylactic composition since it is administered to a horse) comprising an effective dose of viral inhibitors directly to a muzzle of said horse (see treatment of wart on muzzle of said horse, column 28 example 14). The instant claims do not recite "veterinary prophylactic composition" but "prophylactic composition"; the claims do not specify what type of composition, thus a topical composition is included in the scope of prophylactic composition. Furthermore, Applicants provided definition of "prophylactic" as "acting to defend against or prevent something, especially disease; protective" provides the support that the composition of viral inhibitors is a prophylactic composition. This is because the definition states "acting to defend against" which is the function of the viral inhibitor.

Applicants arguments that topical medicaments are inherently meant to be effective and treat only the areas to which they are applied and that once an effective dose of the topical composition is applied it becomes ineffective as soon as it is removed or wiped off the infected area is carefully considered but is not persuasive. The instant claims broadly recite " a prophylactic composition" and the claims do not indicate what type of prophylactic composition. Any type of prophylactic composition is within the scope of "prophylactic composition" and it is noted that claim 29 indicates the composition is applied as paste or salves or films which are topically applied. Thus, it is assumed Applicants composition applied as pastes or salves or films are enabled and will be effective. The Office does not agree that topical medicaments are inherently meant to be effective and treat only the area to which they are applied. Pastes or salves of claim 29 are topical applied to the muzzle but this does not mean that they only treat the muzzle. Furthermore, there is nothing in Squires et al to suggest that the topical composition will be harmful to the animal when ingested and thus is speculation not supported by the teachings of Squires et al. Thus, the prophylactic composition of Squires et al can be applied to the oral or nasal mucosa indicating that it will be effective to defend against papilloma virus warts and other infectious diseases (see column 7 lines 1-13).

Furthermore, the claims do not specifically recite what the effective dose is effective for once its distributed into the oral and/or nasal cavity. Thus, the effective dose of the composition can be effective topically since the claims do not indicate that the effective dose is only effective (for what?) when distributed into the oral and/or nasal mucosa.

As to Reynolds et al Applicants argue that the disappearing dye in Reynolds does not function as a post-application identifier because the dye actually disappears thereby rendering it

useless post application. This is not persuasive. Reynolds et al teaches skin treatment products such as a drug that comprises a light visible dye that changes from one color to another color (light-visible dye) or colored dyes that become invisible or colorless after application to the skin (non-visible dye) which ensures uniform application to the skin for complete coverage of a desired area. See column 1 lines 10 to 17, lines 60-67, and column 2 lines 54 to 67. column 4 lines 5 to 8 and lines 35 to 48). There is no requirement in claims 27, 34 and 35 of how the post-application identifier is identified. Reynolds's dyes are post application dyes because they change color from one color to another color after application to the skin or become invisible or colorless after application to the skin and so are useful as post application identifiers.

18. The rejection of claims 23, 28-30 and 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Squires et al US 6,350,784 B1 Fe. 26, 2002 and Reynolds et al US 5,753,244 May 19, 1998 as applied to claims 17, 22, 25, 26, 27, 32, 34 and 35 above, further in view of Callaghan et al US 6,410,062 B1 (June 25, 2002 filed Jun. 2, 2000) is maintained.

Applicant's arguments are essentially for the same reasons set forth above for Squires in view of Reynolds and have been addressed above.

Status of Claims

Claims 14 and 14 are withdrawn.

Claims 23 and 27-35 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUWATOSIN OGUNBIYI whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am- 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/David J Blanchard/
Primary Examiner, Art Unit 1643